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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 23

Application Number: 09/314,497
Filing Date: May 19, 1999
Appellant(s): SCHINDLY ET AL.

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For Appellant

EXAMINER'S ANSWER

This is in response to the supplemental appeal brief filed 06/23/2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that

there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existance of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The amendment after final rejection filed on 10/29/2002 has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1, 8, 15, 19, 20, 21, and 23 stand or fall together because appellant's brief does include a statement that this grouping of claims does not stand or fall together but fails to provide reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,997,814	Minerovic et al.	12-1999
6,287,518	Ignacio et al.	9-2001

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minerovic et al (U.S.P.N. 5,997,814) in view of Ignacio et al (U.S.P.N. 6,287,518).

With respect to claims 1, 8, 15, 19-21 and 23, Minerovic teaches a package (col.2, line 12), which can be used in a single application, for holding a powdered composition (col.2, line 12), which forms a solution of an anti-microbial decontaminate when mixed with water (col.2, lines 13-14) and for selectively releasing the composition (col.3, lines 60-62) the package includes the following: a porous portion (col.5, lines 63-67, and col.6, lines 33-35), which is impermeable to the first and second components but is permeable to water and to solutions containing dissolved components (col.8, lines 57-62), a side wall (figure 4, 50), a bottom wall (figure 4, 58), a top cover across an upper portion of the side wall that defines a porous portion (figure 4, 94 and col.9, lines 34-35). Minerovic goes on to teach a system including: a well (figure 2, 16) for receiving the package of claim 1, source of water connected with the well (col.5, lines 9-16) for mixing with the powdered composition to form the antimicrobial solution, a microbial decontamination chamber (figure 2, C) connected with the well for receiving the anti-microbial solution and the well the porous region and the chamber forming a re-circulating fluid flow path for the decontaminate solution (col.4, lines 66-67, and col.5, lines 1-31), a cup (figure 4, C), a porous portion connected to the cup (figure 4, 94), a source of water connected with an inlet to the well (figure 2, unlabeled inlet) and a fluid line connecting the chamber with the well outlet (figure 2, unlabeled outlet). Minerovic further discloses a package for releasing an antimicrobial composition into a flowing liquid including: side wall (figure 3, 52) having a first opening (figure 3, 56) at a first end and a second opening (figure 3, 60) at a second end such that the liquid flows through the first opening into the package and out through the second opening, layer of porous

material (figure 4, 94) spanning one of the first and second openings such that the liquid flows through the porous material layer (figure 2,C, 16, 28, 24, 14 and 12), an antimicrobial source is disposed within the package (figure 4, 88) for releasing the antimicrobial composition into the flowing liquid (figure 2,C, 16, 28, 24, 14 and 12) to form an antimicrobial solution. Minerovic further teaches of a method including all the limitations mentioned above (columns 10-12). In addition, Minerovic teaches of using measured amounts of the reagents to form the required concentration of the sterilant to effect sterilization (col.2, lines 1-3) and also uses the word "metering" preselected amounts of both reagents (col.3, lines 24-45). However, with respect to claims1, 8, 15, 19-21 and 23, Minerovic fails to disclose placing an indicator on the package. Ignacio teaches the use of an indicator, which exhibits a detectable change on exposure to the decontaminant in the solution (col.1, lines 47-52). Furthermore, Ignacio teaches that the location of the indicator can be placed any where on the single-use package (col.9, lines 54-62) including on a porous portion of the top cover or the like. Thus, it would have been obvious to one having ordinary skill in the art to modify Minerovic's package and method to include an indicator in order to insure that sterilization processes are effective and meet certain pre-determined sterilization parameters (Ignacio et al, col.1, lines 17-20 and lines 62-67).

With respect to claims 2-7, and 22, Minerovic teaches the following: a first compartment for receiving a first component of the composition, a second compartment for receiving a second component of the composition (col.2, lines 27-30), the porous portion, first compartment, and second compartment configured for forming a fluid flow

path for the decontaminate solution through the package (col.6, lines 52-60, and col.10, lines 12-27), an outer, first cup (figure 3, 50), including a first peripheral wall (figure 3, 52) with an opening at an end (figure 3, 60), the first peripheral wall being at least selectively water transmissive (col.8, lines 8-17), inner second cup (figure 3,70), including a second peripheral wall (figure 3,72), second peripheral wall being at least selectively water transmissive or water permeable (col.8, lines 24-27), the first and second cups being configured such that the second peripheral wall abuts (figure 4, 74) and is connected to the first cup (figure 4, 54) adjacent the end of the first peripheral wall (figure 4, 52), top cover (figure 4, 94), covering the openings in the first and second cups, such that the first compartment (figure 4, 88), is defined in the first cup (figure 4, 50), and the second compartment (figure 4,not labeled) is defined in the second cup (figure 3, 70), first peripheral wall includes a region which is formed from a first material (col.9, lines 54-56), first cup peripheral wall includes a side and a base (figure 3, 50, 52 and 60) and wherein the base is detachable from the side (figure 4, 58), second peripheral wall (figure 4, 72) includes a region which is formed from a second material (col.9, lines 56-57), which is impermeable to the first and second components but is permeable to water and to solutions containing dissolved components (col.8, lines 57-62), second peripheral wall defines a hemisphere and is formed from the second material (figure 4, 72).

With respect to claims 9-10, Minerovic teaches the following: porous portion is formed from non-woven polypropylene web (col.6, lines 24-27), decontaminate includes

peracetic acid (col.7, line 10), first component includes acetylsalicylic acid and the second component includes sodium perborate (col.10, lines 1-3).

With respect to claims 11-14, Ignacio teaches the following: various time contacts (see examples 1-6), indicator is specific for the decontaminant (abstract, lines 4-5), indicator is less sensitive to PH than to the decontaminant (col.7, lines 1-3 and also Ignacio et al shows various concentration ranges which inherently constitutes various PH values where the indicator is functioning), indictor is impregnated into the porous portion in the form of an ink (figure 1, 40 and col.4, lines 14-18) and where the indicator exhibits a detectable color based on proper concentration and time (col.1, lines 62-67).

With respect to claims 16-18, Ignacio teaches the following: the decontaminant is peracetic acid (col.1, lines 45-47) and the indicator provides a detectable color change when the peracetic acid is at a concentration of about 900ppm for a preselected period of time (col.8, table showing the various concentrations of peracetic acid), the indicator is bromocresol green (col.6, line 38), and the indicator is crystal violet (col.6, line 31).

(11) Response to Arguments Regarding The New Statement of The Rejection

On page 4 of the brief, appellant argues that, "This statement is either very misleading or represents a misunderstanding of the term package as used in the two references".

The statement on page 4 of the non-final rejection dated 04/22/2003 refers to the package of Minerovic et al not to the package of Ignacio et al. Please note this rejection

is based on Minerovic et al in view of Ignacio et al. Thus, the statement is clear and is not misleading.

On page 5 of the brief, appellant argues that, "It makes no suggestion and provides no motivation to attach a chemical indicator to the source of the sterilant material".

Ignacio et al discloses range of possibilities for placing the indicator. Thus, it would have been obvious to one having ordinary skill in the art to place the indicator close or far (in the sterilization chamber close to the source of the sterilant) from the item to be sterilized. See col.9, lines 55-59. As a result, whether the indicator is placed close to the source of sterilant or far from the source of sterilant will be within the scope of the Ignacio et al reference.

(12) Response to Argument

Issue 1

On page 6 of the brief, appellant argues that, "placing an indicator in a sterilization chamber either on or along with items to be sterilized would not suggest to one of ordinary skill in the art that an indicator should be placed elsewhere in a sterilizer".

Ignacio provides range of possibilities for placing the indicator in the chamber (col.9, lines 55-59). It would have been obvious to one having ordinary skill in the art to place the indicator close or far (in the sterilization chamber close to the source of the sterilant) from the item to be sterilized. Thus, whether the indicator is placed close to

the source of sterilant or far from the source of sterilant is a routine experimentation based on the range of possibilities for placing the indicator provided by Ignacio.

On page 7 of the brief, appellant argues that, "Ignacio makes no suggestion of placing an indicator on a single-use sterilant supplying package, or indeed on any package which holds a powdered composition for forming a solution of antimicrobial decontaminant".

Ignacio provides wide range of locations for the indicator. For example, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge. In addition, Minerovic and the application use peracetic acid (specification, page 14) as the antimicrobial decontaminant.

On page 7 of the brief, appellant argues, "Ignacio does not teach that the indicator should be placed well away from the item to be sterilized, such as any where on a single-use sterilant source package where sterilant concentrations as the reagents mix with water to create the sterilant solution are much higher than at the items or elsewhere in the system".

Ignacio teaches that the indicator can be placed directly on the item or placed on the package containing the item, or along with the item in the chamber without specifying exactly where in the chamber. Thus, the indicator can be placed any where in the chamber close or far from the source of the sterilant resulting in detection of high levels or acceptable levels of the sterilant at the source or away from the source of the sterilant.

On page 8 of the brief, appellant argues, "A review of figures 2 and 4 of the application reveals this statement is clearly in error".

The examiner acknowledges that error was a typo error. The examiner intended to write the following: If the indicator is put on the surface 72, then it is remote from the item. In addition, the claims are silent with regard to distance from the items to be sterilized.

On page 8 of the brief, appellant argues, "Appellants maintain that, to the contrary, generations of experimentation have shown that the indicator must be place in a position where it experiences as close to the identical exposure conditions as the items being sterilized to such a degree that it is now the conventional wisdom in the art".

As explained above, Ignacio discloses range of possibilities for placing the indicator. For example, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge or another possibility is to place the indicator along with the item in the chamber without indicating exactly where in the chamber such that the indicator can be placed far from the source of the sterilant resulting in detection of acceptable levels of the sterilant.

On page 8 of the brief, appellant argues with respect to the concept of placing a monitor on the sterilant source.

The examiner still maintains the position that the claims are silent with regard to the concept of placing a monitor on the sterilant source. Also, the examiner maintains that the claims are analyzed in the broadest interpretation.

On page 9 of the brief, appellant argues, "Minerovic's cartridge C is not placed in a sterilization chamber with the items".

As explained above, Ignacio discloses wide range of locations for the indicator including the placement of the indicator on the source of the sterilant of Minerovic's cartridge regardless of the location of the cartridge. Again, the claims are silent with respect to the concept of placing the indicator on the sterilant source.

On page 10 of the brief, appellant argues, "Appellants maintain that there is no teaching in Ignacio or Minerovic of placing an indicator on a single use package, such as that of Minerovic, which is well away from the sterilization process.

Ignacio teaches wide range of locations for the indicator, which includes placing the indicator on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59). Furthermore, the Minerovic reference is well away from the sterilization process (figure 2, C and 14).

On page 11 of the brief, appellant argues, "Ignacio teaches that the indicator should be close to the item, where it can measure the process conditions experienced by the item".

Ignacio provides wide range of locations for the indicator. For example, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge, which is away from the item to be sterilized (figure 2, C and 14).

On page 11 of the brief, appellant argues, "The teaching of Ignacio might suggest to one of ordinary skill in the art to place an indicator on the tray 14 of Minerovic, but not well away from the items being sterilized, such as on Minerovic's cartridge C".

Ignacio teaches wide range of locations for the indicator, which includes placing the indicator on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59).

On page 12 of the brief, appellant argues, "Neither Minerovic nor Ignacio recognizes the problem of losing indicators, the problem of having an indicator go through a cycle multiple times and the problem of operators who forget to add an indicator".

Examiner maintains that the claims are silent with respect to such concepts.

On page 13 of the brief, appellant argues, "Ignacio fails to teach or fairly suggest placing a sterilization indicator on the sterilant generating package of Minerovic".

Ignacio teaches wide range of locations for the indicator, which includes placing the indicator on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59).

Issue 2

On page 13 of the brief, appellant argues, "Ignacio provides no motivation for locating a sterilization monitor remote from the sterilized item, at which remote location it would not necessarily be expected to be a reliable indicator that the item was sterilized".

Ignacio teaches wide range of locations for the indicator, which includes placing the indicator on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59).

Thus, it would have been obvious to one having ordinary skill in the art to place the indicator close or far from the item to be sterilized.

On page 13 of the brief, appellant argues, "the problem sought to be solved was not recognized by Ignacio or Minerovic".

Examiner maintains that the claims are silent with respect to such concepts.

On page 14 of the brief, appellant argues, "Ignacio makes no suggestion of placing chemical indicators anywhere except with the items being sterilized, such as on a porous package which holds the sterilized items".

Ignacio teaches wide range of locations for the indicator, which includes placing the indicator on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59).

Issue 3

On page 14 of the brief, appellant argues, "Ignacio teaches away from placing an indicator on a porous portion of a package which releases a concentrate for forming a decontaminant".

As explained above, Ignacio discloses range of possibilities for placing the indicator (col.9, lines 55-59). For instance, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge.

On page 14 of the brief, appellant argues, "Ignacio does not teach or fairly suggest placing a chemical indicator in a location where those of ordinary skill in the art would expect it to sense significantly different antimicrobial agent concentrations than are seen by the items being sterilized".

Ignacio provides range of possibilities for placing the indicator in the chamber (col.9, lines 55-59). It would have been obvious to one having ordinary skill in the art to place the indicator close or far (in the sterilization chamber close to the source of the sterilant) from the item to be sterilized. Thus, whether the indicator is placed close to the source of sterilant or far from the source of sterilant is a routine experimentation based on the range of possibilities for placing the indicator provided by Ignacio.

On page 15 of the brief, appellant argues, "The examiner asserts that Ignacio teaches placing the indicator interior to the package where it would be in direct contact with one component of the concentrate".

Ignacio provides range of possibilities for placing the indicator in the chamber (col.9, lines 55-59). It would have been obvious to one having ordinary skill in the art to place the indicator close or far (in the sterilization chamber close to the source of the sterilant) from the item to be sterilized. Thus, whether the indicator is placed close to the source of sterilant or far from the source of sterilant is a routine experimentation based on the range of possibilities for placing the indicator provided by Ignacio.

Issue 4

On page 15 of the brief, appellant argues, "Ignacio mentions crystal violet lactone as one of an extensive list of different dyes, without drawing particular attention thereto".

Ignacio provides various types of dyes. Such dyes are common knowledge to a person in the art. However, choosing a dye is well within the scope of an artisan.

Issue 5

On page 16 of the brief, appellant argues, "Ignacio does not teach or fairly suggest the placement of chemical indicators in areas displaces from the items being sterilized, which areas could not necessarily be expected to see the same exposure conditions as the items to be sterilized".

Ignacio teaches wide range of locations for the indicator. For instance, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59). Furthermore, the Minerovic reference discloses that the package is well away from the sterilization process (figure 2, C and 14) in the mixing well.

Issue 6

On page 17 of the brief, appellant argues, "Ignacio does not suggest putting an indicator on a porous portion of a package for releasing an anti-microbial composition".

Ignacio teaches wide range of locations for the indicator. For instance, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59).

On page 17 of the brief, appellant argues, "Appellant maintains that one skilled in the art would not be motivated, in view of Ignacio, to place an indicator at the source of the concentrate, where it could not necessarily be expected that the concentration to which it is exposed will be identical to that to which the items to be sterilized are exposed".

Ignacio teaches wide range of locations for the indicator. For instance, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59).

Issue 7

On page 18 of the brief, appellant argues, "Appellants maintain that the reference of record would not motivate one of ordinary skill in the art to impregnate a porous portion of a cartridge with an indicator as claimed".

Ignacio teaches wide range of locations for the indicator. For instance, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59).

On page 18 of the brief, appellant argues, "Ignacio suggests placing indicators near items which are the recipient of already diluted decontaminant solutions, but provides not motivation to place an indicator at the source where concentrations may be expected to reach higher levels.

Ignacio teaches wide range of locations for the indicator. For instance, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge (col.9, lines 55-59).

On page 18 of the brief, appellant argues, "it is submitted that Ignacio teaches against placing an indicator at the antimicrobial source in favor of placing the indicator in

locations where it will be assured of experiencing the same exposure temperature, the same exposure peracid concentration, and the same exposure time as the items to be treated".

Ignacio provides range of possibilities for placing the indicator in the chamber (col.9, lines 55-59). It would have been obvious to one having ordinary skill in the art to place the indicator close or far (in the sterilization chamber close to the source of the sterilant) from the item to be sterilized. Thus, whether the indicator is placed close to the source of sterilant or far from the source of sterilant is a routine experimentation based on the range of possibilities for placing the indicator provided by Ignacio.

Issue 8

On page 19 of the brief, appellant argues that, "This much quoted section of Ignacio provides no motivation to remove the indicator from the sterilization chamber and position it in another location in the sterilizer, much less the well of other location which receives and dilutes the concentrated sterilant and which distributes it in its diluted form to the sterilization chamber".

Ignacio et al discloses range of possibilities for placing the indicator. Thus, it would have been obvious to one having ordinary skill in the art to place the indicator close or far (in the well close to the source of the sterilant) from the item to be sterilized. See col.9, lines 55-59. As a result, whether the indicator is placed close to the source of sterilant (well) or for far from the source of sterilant (sterilization chamber) is a routine experimentation based on the range of possibilities for placing the indicator provided by Ignacio et al. Furthermore, Ignacio et al provides wide range of locations for the

indicator. For example, "indicator can be placed within the sterilization chamber" does provide that one of the possibilities for the indicator is to be placed on the source of the sterilant of Minerovic's cartridge in the well.

Respectfully submitted,

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